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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/541,376	03/31/2000	Robert Justice Shartle	LFS-105	3494

7590 07/16/2004

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/541,376	SHARTLE, ROBERT JUSTICE	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Naka et al (EP 803,288, submitted in the Information Disclosure Statement filed on November 25, 2002).

Naka et al teach of a device for analyzing a sample, which comprises a body 5 having a base member 5b and a cover 5a. In the upper surface of the base member is located a sample inlet 4, a first capillary channel 2a for conveying a sample from the inlet to a branching point 6a (see Figures 3, 4, 5a-5d), an analytical section 3 which contains therein a reagent for reacting with the sample and which serves as a first stop junction, a second capillary channel 2b, and a suction pressure generating chamber 1. A bypass channel 6 branches from a portion of the drawing channel 2a between the opening 4 and the analytical section 3, and extends to communicate with the suction pressure generating chamber 1. The device is formed by the lamination of a plurality of films that contain cutouts therein. See Figure 10. The cutouts in the layers form the sample inlet, channels, measurement area, and bypass channel. Naka et al teach that some layers of the device can be transparent to facilitate the optical measurement of the sample therein. A second stop flow junction in the bypass channel 6 is formed by the abrupt change in cross section of the bypass channel 6 at 6a where an angle is formed that points toward the drawing channel 2a. This second stop flow junction separates the region 6a from the overflow region 6. In figures 5a-5d, it is shown how the second stop flow junction is weaker than the first stop flow junction such that excess sample passes through the second stop junction

into the overflow region only after a sample has filled the measurement area 3. In using the device taught by Naka et al, a portion of the covering corresponding to the suction pressure generating chamber 1 is compressed by applying a pressure. Then, in this state, the opening 4 is contacted with a sample. The pressure applied to the chamber is released by weakening the force so that the compressed portion of the covering can return to its original shape due to the elasticity of the covering. Sample is drawn first into the drawing channel 2a and measurement section 3 since the liquid flow resistance Z in the drawing channel 2a between the branching portion of the bypass channel 6 and the measurement section 3 is the smallest. If an excess of suction pressure still remains, because the liquid flow resistance Y in the bypass channel 6a is smaller than the liquid flow resistance X in the drawing channel 2b, an excess amount of sample will flow into the bypass channel 6 as shown in Fig. 5B.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al (EP 803,288) in view of Shartle et al (EP 974,840, submitted in the Information Disclosure Statement filed November 25, 2002). For a teaching of Naka et al, see previous paragraphs in this Office action. Naka et al fail to teach of using the device for the measurement of blood clotting parameters.

Shartle et al teach of a medical diagnostic device that permits the measurement of analyte concentration or a property of a biological sample, particularly the coagulation time of blood. The device comprises a first and second layer, at least one of which has a resilient region therein, separated by an intermediate layer, in which cutouts in the intermediate layer form, with the first and second layers: a) a sample port for introducing a sample of biological liquid into the device, b) a measurement area in which a physical parameter of the sample is measured and related to analyte concentration or property of the sample, c) a first channel providing a path from the sample port to the measurement area, d) a bladder at the second end of the first channel comprising at least a part of the resilient region and having a volume that is at least about equal to the combined volume of the measurement area and first channel, e) a stop junction in the first channel between the measurement area and the bladder, and f) a bypass channel that provides an additional path from the first channel to the bladder without traversing the measurement area and stop junction. See Figures 6 and 6a-6c in Shartle et al. The measurement area includes a reagent to react with the sample fluid. The first or second layer is substantially transparent so that the physical property which is measured is optical transmission through the measurement area. The biological fluid analyzed with the device can be whole blood, and prothrombin time can be measured. In this case, the measurement area contains thromboplastin therein. Alternate fluid

paths can also be located in the device from the first channel to the bladder. Each alternate path has its own measurement area and stop junction. In the device depicted in Figure 7, the measurement area 118P contains thromboplastin. Measurement area 218P contains thromboplastin, bovine eluate and recombinant factor VIIa, which is selected to normalize the clotting time of a blood sample by counteracting the effect of an anticoagulant. Measurement area 318P contains thromboplastin and bovine eluate alone, to partially overcome the effect of an anticoagulant.

Based upon a combination of Naka et al and Shartle et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the device taught by Naka et al for the measurement of blood clotting parameters since Shartle et al disclose that similar fluidic devices containing capillary channels, measurement regions and stop flow junctions therein, which have the same overall structure as the device taught by Naka et al, can be used to measure blood clotting parameters, particularly prothrombin time.

6. Applicant's arguments filed May 6, 2004 have been fully considered but they are not persuasive.

Applicant argues the rejection of the claims under 35 USC 102(b) as being anticipated by Naka et al and under 35 USC 103 as being obvious over Naka et al in view of Shartle et al by stating that the primary reference to Naka et al teaches that it is the bypass channel 6a itself that serves to impede sample flow into overflow capillary 6 until measurement area 3 is filled due to its small diameter and relatively long length, not the juncture of the overflow region 6 with the capillary channel 6a. In response to this argument, it is noted that Applicant is partially correct in stating that the diameter and length of the bypass channel 6a are responsible for impeding the

flow of fluid from the channel 2a to the overflow region 6. However, it is not only the diameter and length of the channel 6a that is responsible for impeding fluid flow, but also the diameter and length of channel 6 in relation to the diameter and length of channel 6a. It is specifically the juncture between the smaller diameter channel 6a and the larger diameter channel 6 that impedes the flow of fluid to the overflow region 6 until measurement area 3 is filled, as depicted in Figures 5a-5d of Naka et al. It is in the area of differing diameters or cross-sections between channels 6a and 6 that the sample flow is stopped until measurement area 3 is filled, thus fulfilling the requirements of amended claim 1. This is similar to the first stop junction in the device taught by Naka et al formed by the different diameter regions between measurement area 3 and channel 2b. In addition, it is noted that the passages from Naka et al cited by Applicant on page 6 of the response do not support the argument that the operative flow resistance in the bypass channel 6a is due only to the bypass channel being relatively long and having a small diameter.

For the above reasons, Applicant's arguments are not found persuasive.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

July 12, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted]1700